K091367

NOV - 5 2009

Section 5: 510(k) Summary

Device Information:

Category	Comments
Sponsor:	Guided Delivery Systems, Inc 2355 Calle de Luna Santa Clara, CA 95054
Correspondent Contact Information:	Bonnie McInerney, Quality Manager Guided Delivery Systems, Inc 2355 Calle de Luna Santa Clara, CA 95054 Tel: 408 727 1105 x227 Fax: 408 727 6615 Email: bmcinerney@gdsmed.com
Device Common Name:	Cardiac Introducer Sheath
Device Classification Number:	21 CFR §870.1340
Device Classification & Product Code:	Class II (two) DYB
Device Proprietary Name:	GDS-DC6

Predicate Device Information:

Predicate Device:	Convoy Advanced Delivery Sheath Kit
Predicate Device Manufacturer:	Boston Scientific Corporation
Predicate Device Premarket Notification #	K072719
Predicate Device Common Name:	Cardiac Introducer Sheath
Predicate Device Classification & Name:	21 CFR §870.1340; Catheter introducer
Predicate Device Classification & Product Code:	Class II (two) DYB

Predicate Device Information:

Predicate Device:	Softouch Diagnostic Intravascular Catheter
Predicate Device Manufacturer:	Merit Medical Systems, Inc.
Predicate Device Premarket Notification #	K000659
Predicate Device Common Name:	Angiographic Catheter
Predicate Device Classification & Name:	21 CFR 870.1200 Diagnostic intravascular catheter
Predicate Device Classification & Product Code:	Class II (two) DQO

b. Date Summary Prepared
May 6, 2009 (revised September 17, 2009)

c. Description of Device
GDS-DC6 is a polymeric, single use, sterile, non-pyrogenic, disposable intracardiac catheter of various sizes and curvatures.

d. Intended Use
GDS-DC6 is intended to facilitate the intracardiac placement of interventional devices such as guidewires.

e. Comparison to Predicate Device
The GDS-DC6 is substantially equivalent in intended use, technology, design and materials to the predicate devices. The testing described below demonstrates that the differences in the devices do not raise any unresolved issues of safety or efficacy. Therefore, Guided Delivery Systems, Inc. concludes that the devices are substantially equivalent.

f. Summary of Supporting Data
Biocompatibility data demonstrates that the device is in compliance with ISO 10993.

Bench testing data has demonstrated that the device is in compliance with ISO 10555-1, the expectations of the medical community and the product labeling.

Packaging and shelf life testing demonstrates that the device packaging is robust and maintains a sterile barrier for the stated expiration time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV - 5 2009

Guided Delivery Systems, Inc.
c/o Ms. Bonnie McInerney
Manager, Regulatory Affairs and Quality
2355 Calle de Luna
Santa Clara, CA 95054

Re: K091367
Trade/Device Name: GDS-DC6 Catheter
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: October 30, 2009
Received: November 2, 2009

Dear Ms. McInerney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number K091367

Device Name: GDS-DC6

Indications for Use:

GDS-DC6 is intended to facilitate the intracardiac placement of interventional devices such as guidewires.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Ve...
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091367